

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PAULA M. HOUCK, et al.,

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Plaintiffs,

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v.

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Civil Action No. GLR-20-3122

ETHICON INC., et al.,
et al.,

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Defendants.

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MEMORANDUM OPINION

THIS MATTER is before the Court on Defendants Ethicon, Inc. and Johnson & Johnson’s (collectively, “Ethicon”) Motion for Summary Judgement (ECF No. 86). The Motion is ripe for disposition, and no hearing is necessary. See Local Rule 105.6 (D.Md. 2023). For the reasons outlined below, the Court will grant the motion in part and deny the motion in part.

I. BACKGROUND

A. Factual Background¹

The FDA issued a notice regarding “serious complications . . . associated with transvaginal placement of surgical mesh to treat . . . stress urinary incontinence” in October 2008. (2008 FDA Notice at 2, ECF No. 86-2). Plaintiff Paula Houck suffered from stress urinary incontinence and read information on the internet regarding vaginal mesh

¹ Citations to exhibit page numbers refer to the pagination assigned by the Court’s Case Management/Electronic Case Files (“CM/ECF”) system.

complications. (Pl. Fact Sheet [“PFS”] at 6, ECF No. 86-3; Paula Houck Dep. at 96:20–101:8, ECF No. 87-2). Houck visited Dr. Daniel Kim on January 22, 2008 to discuss treatment options. (Daniel Kim, M.D. Dep. [“Kim Dep.”], at 27:6–30:5, ECF No. 87-1). On June 3, 2009, Dr. Kim implanted Houck with Ethicon’s vaginal mesh product, the tension-free vaginal tape obturator (“TVT-O”), as an attempted treatment, (*id.* at 112:8–22), which he informed her was the gold standard in the industry, (Paula Houck Dep. at 100:11–17). During a follow-up visit in August 2009, Dr. Kim observed that Houck had possible mesh exposure. (*See* Kim Dep. at 50:21–51:11). After post-surgery pain persisted, Houck and Dr. Kim discussed removing the mesh on June 29, 2010, and Dr. Kim performed a removal surgery on August 6, 2010. (*Id.* at 52:19–53:20, 121:5–123:23). From 2010 to 2018, Houck had multiple additional surgeries, attempting to relieve her pain and urinary incontinence as well as remove remaining portions of the mesh. (Expert Report of Daniel Elliott, M.D. at 34–46, ECF No. 87-3). Houck’s pain continues to this day. (PFS at 7–8).

B. Procedural History

Plaintiffs Paula Houck and Gary Houck (collectively, “Houck”) filed a short-form complaint on November 26, 2012 in the United States District Court for the Southern District of West Virginia, alleging injuries arising out of Paula Houck’s implantation of TVT-O to treat her stress urinary incontinence. (ECF No. 1). The case was consolidated with others into MDL 2327, In re Ethicon, Inc., Pelvic Repair System Products Liability

Litigation MDL (Civil Case No. 2:12-MD-02327) in the United States District Court for the Southern District of West Virginia. (See Pretrial Order at 8, ECF No. 16). On October 13, 2020, the MDL Judge transferred this case to the Court via transfer order. (ECF No. 56).

On July 1, 2021, the parties filed a Joint Stipulation of Partial Voluntary Dismissal as to the following claims: a separate manufacturing defect claim (Counts I, in part; II; and XIV, in part); strict liability—defective product (Count IV); negligent infliction of emotional distress (Count X); violation of consumer protection laws (Count XIII); and unjust enrichment (XV). (Stipulation of Dismissal at 1, ECF No. 84). The remaining contested claims are: negligence (Count I, in part as to failure to warn and design defect); strict liability—failure to warn (Count III); strict liability—design defect (Count V); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); breach of warranty (Counts XI and XII); gross negligence (Count XIV, in part as to failure to warn and design defect); and, loss of consortium (Count XVI). The parties agree that Maryland law controls the substantive claims here. (Mem. Supp. Partial Mot. for Summ. J. at 3, ECF No. 47; Resp. Opp’n to Mot. Partial Summ. J. at 5, ECF No. 50).

On July 7, 2021, Ethicon filed a Motion for Summary Judgment. (ECF No. 86). Houck filed an Opposition on July 28, 2021. (ECF No. 87). Ethicon filed a Reply on August 11, 2021. (ECF No. 88). Houck filed a Motion for Trial Setting on July 11, 2023.

(ECF No. 90). Ethicon filed an Opposition only insofar as it requested the Court to first consider the Motion for Summary Judgment. (Opp’n Mot. Trial Setting at 1, ECF No. 92). Houck filed a Reply on August 4, 2023. (ECF No. 93).

II. DISCUSSION

A. Standard of Review

In reviewing a motion for summary judgment, the Court views the facts in a light most favorable to the nonmovant, drawing all justifiable inferences in that party’s favor. Ricci v. DeStefano, 557 U.S. 557, 586 (2009); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986) (citing Adickes v. S.H. Kress & Co., 398 U.S. 144, 158–59 (1970)). Summary judgment is proper when the movant demonstrates, through “particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . admissions, interrogatory answers, or other materials,” that “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed.R.Civ.P. 56(a), (c)(1)(A). Significantly, a party must be able to present the materials it cites in “a form that would be admissible in evidence,” Fed.R.Civ.P. 56(c)(2), and supporting affidavits and declarations “must be made on personal knowledge” and “set out facts that would be admissible in evidence,” Fed.R.Civ.P. 56(c)(4).

Once a motion for summary judgment is properly made and supported, the burden shifts to the nonmovant to identify evidence showing that there is a genuine dispute of

material fact. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586–87 (1986). The nonmovant “must set forth specific facts, either by affidavit or other evidentiary showing, demonstrating a genuine dispute for trial.” Sanchez Carrera v. EMD Sales, Inc., 402 F.Supp.3d 128, 144 (D.Md. 2019). The nonmovant cannot create a genuine dispute of material fact “through mere speculation or the building of one inference upon another.” Othentec Ltd. v. Phelan, 526 F.3d 135, 140 (4th Cir. 2008) (quoting Beale v. Hardy, 769 F.2d 213, 214 (4th Cir. 1985)).

A “material fact” is one that might affect the outcome of a party’s case. Anderson, 477 U.S. at 248; see also JKC Holding Co. v. Wash. Sports Ventures, Inc., 264 F.3d 459, 465 (4th Cir. 2001). Whether a fact is considered to be “material” is determined by the substantive law, and “[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment.” Anderson, 477 U.S. at 248; accord Hooven-Lewis v. Caldera, 249 F.3d 259, 265 (4th Cir. 2001). A “genuine” dispute concerning a “material” fact arises when the evidence is sufficient to allow a reasonable jury to return a verdict in the nonmoving party’s favor. Anderson, 477 U.S. at 248. If the nonmovant has failed to make a sufficient showing on an essential element of his case where he has the burden of proof, “there can be ‘no genuine [dispute] as to any material fact,’ since a complete failure of proof concerning an essential element of the nonmoving party’s case necessarily renders all other facts immaterial.” Celotex Corp. v. Catrett, 477 U.S. 317, 322–23 (1986) (quoting Fed.R.Civ.P. 56(c)). Thus,

summary judgment is warranted if the nonmovant does not provide evidence to establish an essential element of the case. Brocious v. U.S. Steel Corp., 429 F.Supp.3d 82, 86 (D.Md. 2019).

B. Analysis

Ethicon moves for summary judgment on Houck’s claims in their entirety. (Mot. Summ. J. at 2, ECF No. 86). Ethicon argues that Houck’s negligence, strict liability, and fraud claims (Counts I, III, V-IX, XIV, and XVI) are barred by the applicable statutes of limitations; Houck’s failure to warn claims (Counts I and III) fail as a matter of law; Houck’s fraud (Counts VI-IX) and warranty (Counts XI-XII) claims are duplicative of the failure to warn claim and fail as a matter of law; Houck’s “claims” for punitive damages and discovery rule/tolling (Counts XVII and XVIII) should be dismissed for failing to state an independent cause of action; and, if the Court dismisses all of the underlying substantive claims, Gary Houck’s derivative loss of consortium claim (Count XVI) also fails. (Mem. Supp. Mot. Summ. J. [“Mot.”] at 2–3, ECF No. 86-1).

1. Statute of Limitations

Ethicon argues that they are entitled to judgement as a matter of law on Houck’s negligence, strict liability, and fraud claims (Counts I, III, V-IX, XIV, and XVI) because those claims are barred by three-year statutes of limitations. (Mot. at 6–10) (citing Md. Code Ann., Cts. & Jud. Proc. § 5-101). In the context of product liability actions, Maryland’s three-year statute of limitations period begins to run when the plaintiff knows

or, through the exercise of due diligence, should know of (1) the injury, (2) its probable cause, and (3) either manufacturer wrongdoing or product defect. Pennwalt Corp. v. Nasios, 550 A.2d 1155, 1165 (Md. 1988). “‘Clear and unequivocal proof’ of manufacturer wrongdoing or a product defect is not required; rather, express or implied knowledge of each element is sufficient to trigger the limitations period.” Helinski v. Appleton Papers, 952 F.Supp. 266, 269 (D.Md. 1997), aff’d 139 F.3d 891 (4th Cir. 1998) (quoting Pennwalt, 550 A.2d at 1167).

The parties dispute the point in time when Houck could have reasonably been on notice of a product defect. Ethicon argues that Houck’s claims accrued by August 4, 2009, when Houck had “at least inquiry notice” of her claim. (Mot. at 8–9). Houck argues that her cause of action did not begin to accrue until June 29, 2010, as that was “the earliest point in time” when she could have understood the “existence of an injury caused by product defect or manufacturer wrongdoing.” (Resp. Opp’n Mot. Summ. J. [“Opp’n”] at 9, ECF No. 87).

On August 4, 2009, Dr. Kim assessed Houck’s post-implantation symptoms, saw that the mesh sling had become partially exposed, and told Houck that if her pain persisted the “sling may need to be revised.” (Kim Dep. at 50:13–51:18). Dr. Kim noted that mesh exposure could have multiple causes including poor healing, infection, early sexual activity, and loss of estrogen. (Id. at 51:4–11). Houck next visited Dr. Kim on June 29,

2010, complaining of continued pain, (id. at 52:19–25), and Dr. Kim advised her that she had treatment options including “excising the sling,” (id. at 53:14–20).

The Court finds that the record creates genuine issues of material fact as to when Houck reasonably could have known that her injury was caused by manufacturer wrongdoing or product defect. Accordingly, the Court will deny Ethicon’s motion as to whether Houck’s claims (Counts I, III, V-IX, XIV, and XVI) are timely.

2. Failure to Warn

Ethicon challenges Houck’s Failure to Warn Claims (Counts 1 and III). (Mot. at 10–14). To establish a claim for failure to warn, a plaintiff must establish that (1) the defendant owed a duty to warn, (2) the defendant breached that duty, (3) there was a direct causal connection between the defendant’s failure to warn and the alleged injuries, and (4) the plaintiff was harmed. Higgins v. Diversey Corp., 998 F.Supp. 598, 604 (D.Md. 1997) (citing Mazda Motor of Am. v. Rogowski, 659 A.2d 391, 394–96 (Md.Ct.Spec.App. 1995), cert denied, 667 A.2d 342 (Md. 1995)).

First, the Parties contest whether the “learned intermediary” doctrine applies in this case such that Defendants’ duty to warn runs only to the prescribing surgeon, not Houck. Ethicon contends that the learned intermediary doctrine applies, and because Dr. Kim was aware of the purported risks of implementation of the TVT-O and discussed them with Houck, Ethicon is not liable to Houck for failure to warn. (Mot. at 11–12). Houck argues that, though this Court has applied the learned intermediary doctrine, Maryland state courts

have not adopted the doctrine, and the parties agree that Maryland law controls the substantive claims in this case. (Opp’n at 11 (citing Mot. at 1, n.1)). Accordingly, Houck argues that Ethicon owed Houck a duty to warn, which Ethicon failed to adequately do. (Opp’n at 11–12).

The learned intermediary doctrine is applicable here. “Maryland law recognizes the learned intermediary doctrine.” Miller v. Bristol-Myers Squibb Co., 121 F.Supp.2d 831, 838 (D.Md. 2000); see Nolan v. Dillon, 276 A.2d 36, 40 (Md. 1971); Gourdine v. Crews, 955 A.2d 769, 776 (Md. 2008) (noting that Maryland recognizes the “learned intermediary” doctrine with respect to prescription drugs). This Court has previously held that “the learned intermediary doctrine applies in cases involving medical devices, like the TVT device used here.” Campbell v. Ethicon, Inc., No. GLR-20-1356, 2021 WL 6126288, at *6 (D.Md. Dec. 28, 2021) (citing Morris v. Biomet, Inc., 491 F.Supp.3d 87, 104 (D.Md. 2020)). However, Ethicon’s argument that the learned intermediary doctrine applies in this case does not on its own support granting summary judgment on its behalf. Houck alleges that Ethicon failed to warn both her and her health care providers of the risks associated with the mesh products. (Opp’n at 14–19).

The Court finds that the record still creates a question for the jury as to whether Dr. Kim was adequately warned of the risks and what he would have done with stronger warnings. Houck’s Expert, Dr. Daniel Elliott, offers testimony that Ethicon failed to disclose numerous adverse risks and warnings associated with the TVT-O to physicians

that should have been included in the product's Instructions for Use ("IFU"). (Expert Report of Daniel Elliot, M.D. at 4, 27–31, ECF No. 87-3). Houck argues that, according to Dr. Kim's testimony, he was not warned by Ethicon about the long-term risks of TVT-O. (Opp'n at 16). Ethicon argues that Dr. Kim was aware of the relevant risks. (Mot. at 12). Dr. Kim testified that the 2009 IFU did not include proper warnings about pain with intercourse that may not resolve; chronic pain in the groin, thigh, leg, pelvic or abdominal region; recurrence of incontinence; and the potential necessity of revision surgeries. (Kim Dep. at 102:13–103:9). Dr. Kim also testified that the 2009 IFU provided warnings about the risk of mesh exposure and that he was aware of the risks of painful intercourse as a result of TVT-O implantation. (Id. at 24:9–20, 98:25–99:18). This conflicting testimony demonstrates a dispute of fact about whether Ethicon's warnings regarding the TVT-O were adequate.

Ethicon also argues that the Houck failed to present evidence that the allegedly inadequate warnings caused the alleged harm. Ethicon argues that Houck cannot prove that additional information did or would have changed Dr. Kim's treatment decisions, so she cannot establish causation and her failure to warn claim fails as a matter of law. (Mot. at 14). In order to establish causation, the plaintiff must prove that the treating provider, "would have acted differently had he received an adequate warning." McCoy v. Biomet Orthopedics, LLC, 2021 WL 252556, at *27 (D.Md. Jan. 25, 2021); see also Gourdine, 955 A.2d at 782 (stating that "causation" is required for failure to warn claims alleged in strict

liability and negligence). Dr. Kim's testimony, as to whether he would have changed his course of treatment with stronger warnings, is inconsistent. On one hand, he testified that he may have changed his decision had he received a better warning.

Q: Is it fair to say that if you had had those bullet points that we listed in the 2009 IFU, certainly it's something that would have informed your risk/benefit analysis of the product?

A: Yes.

(Kim Dep. at 103:24–104:3).

Q: Is it also fair to say that if you relayed that information to Paula Houck and she told you that she didn't -- she wasn't willing to accept those kinds of risks, you would then not have gone forward with the implant of the TVT-O?

A: Correct.

(Kim Dep. at 104:5–21). However, when asked whether he stood by his decision to implant the TVT-O in June of 2009, Dr. Kim replied, "Yes, I do." (Id. at 153:14–17). This conflicting testimony demonstrates the existence of a genuine dispute of fact as to whether Dr. Kim would have prescribed the TVT-O to Houck had he received a better warning. Accordingly, the Court will deny Ethicon's motion on the failure to warn claims (Counts I and III).

3. Gross Negligence

Ethicon also challenges Houck's claim of gross negligence as to failure to warn and design defect (Count XIV) on the grounds that there is insufficient evidence in the record to support that claim. (Mot. at 10, n.5). Under Maryland law, gross negligence is defined

as: “an intentional failure to perform a manifest duty in reckless disregard of the consequences as affecting the life or property of another, and also implies a thoughtless disregard of the consequences without the exertion of any effort to avoid them.” Beall v. Holloway-Johnson, 130 A.3d 406, 415 (Md. 2016) (citing Barbre v. Pope, 935 A.2d 699, 717 (Md. 2007)). This Court has previously denied similar motions from Ethicon for gross negligence premised on failure to warn or design defect. Kramer v. Ethicon, Inc., No. GLR-20-3747, 2021 WL 6135206, at *7 (D.Md. Dec. 28, 2021).

For the same reasons the Court determined that the failure to warn claims have disputes of material fact, the Court finds that there are disputes of material fact as to whether Ethicon was grossly negligent in its warnings regarding the TVT-O device. Ethicon does not argue that that they are entitled to dismissal of the design defect claim (Count V) other than arguing that the claim is barred by the applicable statute of limitations. The Court finds that there is a question of material fact as to when Houck’s claims accrued, and it will not dismiss the gross negligence claim regarding the design defect where Ethicon made no showing that summary judgement is proper. Accordingly, the Court will deny Ethicon’s Motion as to Houck’s gross negligence claim (Count XIV).

4. Fraud and Warranty

Ethicon moves for summary judgement on Houck’s fraud (Counts VI-IX) and warranty (XI-XII) claims. (Mot. at 14–15). Ethicon argues that Houck’s fraud claims are duplicative and should fail as a matter of law for “the same reasons as the failure to warn

claims fail.” (Mot. at 15). As established above, even when applying the learned intermediary doctrine, there is a question of material fact as to whether Ethicon adequately disclosed the risks of TVT-O to Dr. Kim. Ethicon puts forth no other basis for summary judgement on the fraud, fraudulent concealment, and negligent misrepresentation claims (Counts VI, VII, and IX). (Mot. at 14–15). Accordingly, the Court will deny Ethicon’s Motion on Houck’s claims for fraud, fraudulent concealment, and negligent misrepresentation (Counts VI, VII, IX).

Ethicon argues that Houck’s constructive fraud claim (Count VIII) also fails because there is no confidential relationship between Houck and Ethicon. (Mot. at 16). Under Maryland law, constructive fraud is a breach of “a legal or equitable duty to the plaintiff in a way that tend[s] to deceive others, to violate public or private confidence, or to injure public interests. For constructive fraud’s purposes, a defendant owes an equitable duty to a plaintiff where the parties are in a confidential relationship.” Thompson v. UBS Fin. Servs., Inc., 115 A.3d 125, 138 (Md. 2015) (citations, quotation marks, and footnote omitted). Ethicon argues that Houck cannot establish a confidential or fiduciary relationship with Ethicon. Houck does not argue that Ethicon and Houck were in a confidential relationship, but rather, that Dr. Kim’s relationship with both Ethicon and Houck created a relationship between Ethicon and Houck. (Opp’n at 23). Maryland law is clear that the confidential or fiduciary relationship in claims of constructive fraud must be between the plaintiff and defendant directly. See Thompson, 115 A.3d at 139. Here, there

is no evidence in the record to show that a confidential relationship existed between Ethicon and Houck directly. See Sacchetti v. Ethicon, Inc., No. 2:12-cv-01148, 2016 WL 7320884, at *5 (S.D.W.Va. Dec. 15, 2016) (granting summary judgment as to a constructive fraud claim under Maryland law where plaintiff failed to present evidence of a confidential relationship with Ethicon). After reviewing the record and drawing all inferences in the light most favorable to Houck, the Court finds that Houck has not met her burden of producing “specific facts showing that there is a genuine [dispute] for trial.” Celotex, 477 U.S. at 324. The Court will grant Ethicon’s Motion on Houck’s claim for constructive fraud (Count VIII).

Ethicon also argues that Houck’s warranty claims (Count XI-XII) are duplicative of the failure to warn claim and that Houck failed to give adequate notice of the warranty claim under Md. Code Ann., Com. Law. § 2-607(3). (Mot. at 14–15). Under Maryland law, a plaintiff must provide adequate notice of a breach of a purported warranty to advance her claim. Md. Code Ann., Com. Law. § 2-607(3); Lynx, Inc. v. Ordnance Prods., Inc., 327 A.2d 502, 514 (Md. 1974) (noting it is an “essential condition precedent”). The notice must be provided by the plaintiff and given “prior to the institution of the action.” Lynx, 327 A.2d at 514; see also Morris v. Biomet, Inc., 497 F.Supp.3d 87, 106 (D.Md. 2020) (“[A] lawsuit cannot constitute notice of a breach under Maryland law”) (internal quotation omitted). Houck does not allege that she provided notice to Ethicon and has provided no evidence of such notice. The record does not indicate that Houck gave notice of this claim

to Ethicon, and there does not appear to be, in the record, any variance that would raise a genuine dispute of fact. Houck’s contention that Ethicon may have independently been aware the fact that it delivered a potentially defective TVT-O device to Houck does not defeat the requirement that the plaintiff provide notice of a breach. Accordingly, the Court will grant Ethicon’s Motion on the breach of warranty claims (Counts XI-XII).

5. Punitive Damages, Discovery Rule Tolling, and Loss of Consortium

Ethicon argues that because Houck pleads punitive damages (Count XVII) and discovery rule tolling (Count XVIII) as standalone causes of action, those claims are entitled to summary judgement. (Mot. at 16–17). Houck concedes that these counts do not amount to “claims” but that they are properly pled and are not subject to dismissal at the summary judgement stage. (Opp’n at 23–24). The Court finds, and Ethicon does not contest, that the record establishes sufficient grounds to create jury questions on both the punitive conduct and discovery rule. Accordingly, summary judgement on Houck’s punitive damages and discovery rule tolling counts (Counts XVII and XVIII) is unwarranted.

Ethicon asks for dismissal of the loss of consortium claim (Count XVI) belonging to Paula Houck’s husband, Gary Houck. (Mot. at 17). Ethicon argues that the claim is “derivative” and cannot survive if the underlying claims are dismissed. (*Id.*). Because Houck’s other claims survive at this stage, so too does the loss of consortium claim.

Accordingly, the Court will deny Ethicon's motion as to Houck's loss of consortium claim (Count XVI).

III. CONCLUSION

For the reasons stated above, the Court will deny Ethicon's Motion for Summary Judgement as to Counts I, III, V, VI, VII, IX, XIV, XVI, XVII, and XVIII and will grant the Motion as to Counts VIII, XI, and XII. A separate order follows.

Entered this 8th day of November, 2023.

/s/

George L. Russell, III
United States District Judge